(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 April 2006 (27.04.2006)

PCT

(10) International Publication Number
WO 2006/044640 A1

(51) International Patent Classification:
A61M 29/00 (2006.01)

(21) International Application Number:
PCT/US2005/036991

(22) International Filing Date: 13 October 2005 (13.10.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/619,308	15 October 2004 (15.10.2004)	US
60/632,147	1 December 2004 (01.12.2004)	US
60/636,845	15 December 2004 (15.12.2004)	US
60/711,310	25 August 2005 (25.08.2005)	US

(71) Applicant *(for all designated States except US)*: **BFKW, LLC** [US/US]; BAKER, Randal S., Member, 5060 Michigan, N.E., Ada, Michigan 49301 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BAKER, Randal, S.** [US/US]; 5060 Michigan, N.E., Ada, Michigan 49301 (US). **KEMMETER, Paul, R.** [US/US]; 1995 Wellpoint Court, N.E., Ada, Michigan 49301 (US). **FOOTE, James, A.** [US/US]; 5355 Fulton, Ada, Michigan 49301 (US).

(74) Agent: **VAN DYKE, GARDNER, LINN & BURKHART, LLP**; c/o Frederick S. Burkhart 2851 Charlevoix Drive, S.E., Suite 207, P.O. Box 888695, Grand Rapids, Michigan 49588-8695 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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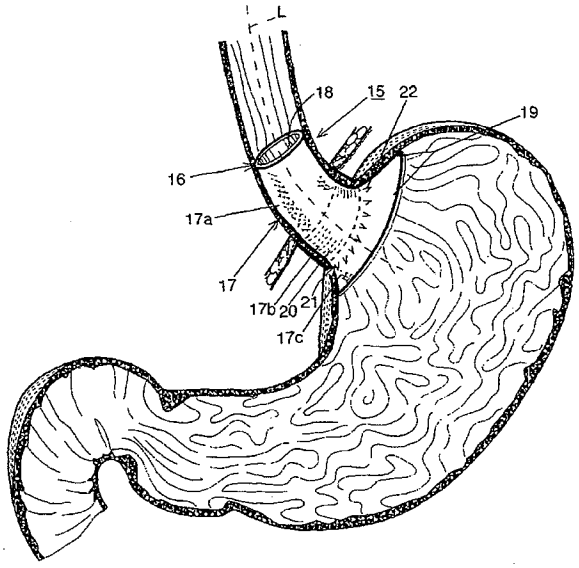
(54) Title: BARIATRIC DEVICE AND METHOD



(57) Abstract: A bariatric device and method of causing satiety in a patient includes providing a body having a wall defining a lumen. The wall is sized to conform to the shape and size of the abdominal portion of the esophagus and/or at the esophageal-gastric junction and/or the proximal cardiac portion of the stomach of the patient. The wall is adapted to exert radial pressure on the abdominal portion of the esophagus and/or the esophageal-gastric junction, and/or the proximal stomach, or cardia, of the patient. This influences the neurohormonal feedback mechanism present at the distal esophagus and the cardia to cause at least partial satiety by augmenting fullness caused by food and simulating fullness in the absence of food.

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Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

— *of inventorship (Rule 4.17(iv))*

Published:

— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

BARIATRIC DEVICE AND METHOD

BACKGROUND OF THE INVENTION

The present invention is directed to a bariatric device and method of causing at least partial satiety in a patient. In particular, the present invention is directed to a bariatric device and a method of causing at least partial satiety in a patient by a noninvasive or minimally invasive technique.

Obesity is a large and increasing problem in the United States and worldwide. In round numbers, from the period encompassing the year 1990 to the period encompassing the year 2000, the prevalence of overweight people (BMI greater than 25) increased from 56 percent of United States adults to 65 percent and the prevalence of obese adults (BMI greater than 30) increased from 23 percent to 30 percent. Likewise, the prevalence of overweight children and adolescents (ages 6-19 years) increased from 11 percent in the period encompassing the year 1990 to 16 percent in the period encompassing the year 2000. The increasing prevalence of overweight among children and adolescents will make the problem even greater when they reach adulthood. The problem is not limited to the United States. Between 10 percent and 20 percent of European men are obese and between 10 percent and 25 percent of European women are obese. Numerous medical conditions are made worse by obesity including Type II diabetes, stroke, gallbladder disease and various forms of cancer. Approximately 500,000 people in North America and Western Europe are estimated to die from obesity-related diseases every year and obesity is estimated to affect more than one billion adults worldwide. Therefore, there is a pressing and unmet need for a solution to the epidemic problem.

Various techniques are known for reducing obesity in patients. Known techniques tend to be based upon restricting food movement and/or nutrient absorption. One example is gastric bypass surgery on the patient, which is highly invasive. The goal of such surgery is to form a pouch from a portion of the stomach to reduce the volume of the space in the stomach receiving food. When the patient ingests food, the pouch is filled which stretches the stomach wall and produces satiety. One difficulty with such procedure is that it requires food to fill the pouch to create satiety. As a result, dietary restrictions are required for effective operation of

the pouch. Such restrictions include withholding of liquids during meals to avoid washing the food from the pouch. Also, liquids with substantial calories tend to pass through the pouch without creating substantial satiety. Moreover, the opening from the pouch tends to become enlarged over time, thus allowing more food to pass while achieving reduced satiety. Thus, patients undergoing such surgical techniques often experience gradual weight gain over time.

Alternative weight loss devices and methods have been proposed. However, such devices and methods may be difficult to place in the patient, have questionable efficacy, and may cause undesirable side effects.

SUMMARY OF THE INVENTION

The present invention utilizes a new principle of implied satietion. The present invention provides a bariatric device and method of causing satiety in a patient that augments the natural response of the body. This may be accomplished using a non-invasive or minimally invasive procedure with a device that may be removable or absorbable. Moreover, satiety may be caused in a manner that does not interfere with other body functions, such as operation of normal reflux mechanism, bile ducts, taking of medications, and the like. The implied satietion technique of the present invention does not rely on either the restrictive or malabsorptive techniques of the prior art.

A bariatric device, according to an aspect of the invention, includes a body having a wall defining a lumen. The wall is sized to generally conform to the shape and size of one or more of the following: i) the abdominal portion of the esophagus; ii) the esophageal-gastric junction; and/or iii) the proximal cardiac portion of the stomach, also known as the cardia. The wall is adapted to exert radial pressure on one or more of i) the abdominal portion of the esophagus; ii) the esophageal-gastric junction; and/or iii) the proximal cardiac portion of the stomach. In this manner, the bariatric device influences a neurohormonal feedback mechanism of the patient to cause at least partial satiety. This is accomplished to augment fullness caused by food, as well as simulating fullness in the absence of food.

The body of the bariatric device may be elongated along a longitudinal axis and be longitudinally non-symmetrical. The body may include at least a portion that is radially non-symmetrical with respect to the longitudinal axis. The wall in any of the bariatric devices above may be sized to generally conform to the size and shape of the abdominal portion of the esophagus, the esophageal-gastric junction and the

proximal cardiac portion of the stomach. Such wall may be adapted to exert radial pressure on at least the abdominal portion of the esophagus and the proximal cardiac portion of the stomach.

The body of any of the bariatric devices set forth above may have first and second portions. The first geometric portion is generally cylindrical and the second geometric portion is generally frusto-conical. The wall of any of the bariatric devices set forth above may include a self-expanding portion that is adapted to exert radial pressure and a substantially non-self-expanding portion that is adapted to not exert radial pressure. The non-self-expanding portion is adapted to be positioned at the gastro-esophageal sphincter.

The wall of the bariatric device in any of the proceeding claims may be adapted to exert a generally constant radial pressure or may be adapted to exert an adjustable radial pressure. A variable radial pressure may be exerted by a chamber in the wall, wherein an amount of fluid in the chamber adjusts the radial pressure exerted by the wall. Such a device may include a port providing external access to the chamber. The device may include a control that is adapted to controlling an amount of radial pressure exerted by the wall. The control may be adapted to temporarily adjust an amount of radial pressure exerted by the wall. In this manner, by way of example, the control may cause the device to exert radial pressure on the abdominal esophagus, gastric-esophageal junction and/or cardia during normal waking hours while relaxing the wall in order to substantially reduce the exerted pressure during non-waking hours when satiety is not required. Such a control achieves useful results including overcoming any potential tachy phylaxis under which, over time, such a device may obtain diminishing returns in satiety for a given amount of radial pressure. This is accomplished by a temporal adjustment that allows the wall to exert more of a radial force during key periods of the day and decreasing radial force when not needed.

Any of the bariatric devices set forth above may include a fixation system that is adapted to resist distal migration of the body. The fixation system may include barbs, V-shaped appendages, metal anchors extending radially from the body, staples, sutures, or the like. The fixation system may include an inflatable anchor bladder. The fixation mechanism may include at least a portion of the body that is adapted to facilitate tissue ingrowth. Such portion may include a series of openings in the portion of the body. Such openings may be a series of distinct

openings or a lattice of smaller openings. The fixation system may be at a portion of the wall that is adapted to be positioned at the esophageal-gastric junction.

Any of the bariatric devices set forth above may include a restriction to resist egress from the lumen. The restriction may be an adjustable restriction. Such an adjustable restriction may include a fluid reservoir that is adjustable by varying fluid in the reservoir. The adjustable restriction may be adjustable by an accessible port for adding to or removing fluid from the reservoir and/or an electronic control device for controlling the amount of fluid in the reservoir.

Any of the bariatric devices as set forth above may include a lumen having a length that is less than 9 cm. The lumen may have a length that is in the range of between approximately 6 cm and approximately 7 cm.

A method of causing at least partial satiety in a patient, according to an aspect of the invention, includes providing a body having a wall defining a lumen and positioning the body at at least one of the following: i) the abdominal portion of the esophagus; ii) the esophageal-gastric junction and/or iii) the proximal cardiac portion of the stomach. Radial pressure is exerted with the wall on the at least one of the following: i) the abdominal portion of the esophagus; ii) the esophageal-gastric junction and/or iii) the proximal cardiac portion of the stomach. The radial pressure influences a neurohormonal feedback mechanism of the patient. This causes at least partial satiety by augmenting fullness caused by food and simulating fullness in the absence of food.

The body may be positioned at the abdominal portion of the esophagus, the esophageal-gastric junction and the proximal cardiac portion of the stomach and exerts radial pressure with the wall on at least the abdominal portion of the esophagus and the proximal cardiac portion of the stomach. A substantially flaccid portion of the wall may be provided with the substantially flaccid portion being positioned at the gastro-esophageal sphincter to reduce interference with the anti-reflux mechanism of the patient.

Any of the methods set forth above may include fixing the body to the patient to resist distal migration of the body. This may include fixing of the body at the esophageal-gastric junction. Such fixing may include facilitating ingrowth of the tissue through the wall of the body.

In any of the methods set forth above, the exerting radial pressure may include exerting a generally constant radial pressure or may include exerting an

adjustable radial pressure. An adjustable radial pressure may be exerted by adjusting the pressure endoscopically or by adjusting the pressure with a control at least partially positioned at the patient, such as in the abdominal cavity. The pressure may be adjusted according to a temporal parameter, such as by decreasing the pressure during expected sleeping periods. This achieves useful results including overcoming any potential tachy phylaxis which, over time, may diminish satiety that is obtained from a particular amount of radial pressure. Thus, during certain periods, such as when the patient is awake, a greater amount of radial force may be exerted, while during sleeping periods, when satiety is not required, the pressure may be decreased. Additionally, pressure may be varied according to the time of day that the patient takes meals.

Any of the methods set forth above may include monitoring of patient satiety caused by the exerting of radial pressure. The monitoring may include monitoring patient satiety during deployment of the body in the patient. A radial pressure may be selected as a function of the monitoring. The monitoring may include monitoring of the activity of the patient's hypothalamus as an indicator of the satiety that is induced in the patient through operation of the neurohormonal feedback mechanism present at the abdominal esophagus, the esophageal-gastric junction and/or the proximal cardiac portion of the stomach.

Any of the methods set forth above may include administering anti-nausea medication to the patient at least during initial deployment of the body. This is to overcome any potential nausea caused, at least initially, by deployment of the body in the patient. Any of the methods set forth above may additionally include administering of nutritional supplements to the patient in order to ensure that the causing of at least partial satiety in the patient does not result in underfeeding of the patient. Such nutritional supplements may include, by way of example, protein supplements. In any of the methods set forth above, the positioning of the body may be done endoscopically and may include fluoroscopic assist.

Thus, it can be seen that the present invention provides an implied satietor and implied satietion method that does not require food to generate the satiety through the neurohormonal mechanism of the body. This advantageously produces at least partial satiety in the patient in the absence of food, as well as augmenting fullness caused by food during the ingestion of the food. Moreover, because satiety is not caused by food, the patient would not necessarily need to be subject to dietary

restrictions, such as withholding of liquids during meals or withholding of liquids having substantial calories. Moreover, in contrast to surgical procedures, the present invention provides a bariatric device and method of causing at least partial satiety that is minimally invasive and which avoids many of the potential side effects of gastric bypass surgery and other surgical procedures, such as adjustable gastric banding, and the like. Also, because of the placement of the device, there is no interference with operation of gastric functions, such as with the bile ducts, and the like. Also, the invention provides a bariatric device and method of inducing at least partial satiety in the patient that does not operate on the basis of causing flu-like symptoms in the patient in a thwarted effort to attempt to induce the patient to eat less such as may occur by the placement of devices in the patient's duodenum, or the like.

Additionally, in contrast to pouches formed in gastric bypass surgery, the present invention does not include a discharge opening that is subject to enlargement with the passage of time, thereby eliminating at least one source of gradual weight gain in patients undergoing gastric bypass surgery.

Moreover, because it is a non-invasive or minimally invasive procedure, the present invention may be applied not only to morbidly obese patients, but to obese patients, overweight patients, adolescents and potentially even children.

Thus, it is seen that the present invention provides a bariatric device and method including a body having an expandable wall which evokes normal neurohormonal responses associated with fullness or satiety. The body wall does so by acting on one or more portions of the distal esophagus and/or the cardia of the patient. The normal filling sensation of the stomach is augmented and amplified.

These and other objects, advantages and features of this invention will become apparent upon review of the following specification in conjunction with the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a diagram of a bariatric device positioned at the abdominal portion of the esophagus, the esophageal-gastric junction and the proximal cardiac portion of the stomach of the patient;

Fig. 2 is a perspective view of an alternative embodiment of the bariatric device in Fig. 1;

Fig. 3 is a bottom plan view of the bariatric device in Fig. 2;

Fig. 4 is the same view as Fig. 2 of another alternative embodiment;

Fig. 5 is the same view as Fig. 4 illustrating an alternative control technique;

Fig. 6 is the same view as Fig. 2 of yet another alternative embodiment;

Fig. 7 is the same view as Fig. 6 illustrating adjustment of restriction;

Fig. 8 is the same view as Fig. 2 of yet another alternative embodiment;

Fig. 9 is the same view as Fig. 2 of yet another alternative embodiment;

Fig. 10 is the same view as Fig. 1 of yet another alternative embodiment;

Fig. 11 is the same view as Fig 1 of yet another alternative embodiment;

Fig. 12 is the same view as Fig. 2 of yet another alternative embodiment;

Fig. 13 is the same view as Fig. 2 of yet another alternative embodiment;

Fig. 14 is the same view as Fig. 2 of yet another alternative embodiment; and

Fig. 15 is a block diagram of a technique for selecting the level of radial pressure exerted by the body wall.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now specifically to the drawings, and the illustrative embodiments depicted therein, a bariatric device, or implied satietor, 15, which causes satiety by acting on the abdominal portion of the esophagus, and/or the esophageal-gastric junction and/or the proximal cardiac portion of the stomach, is illustrated in Fig. 1 being positioned in the patient. Device 15 includes a body 16 having a radially expandable wall 17 thereby defining a transverse passage, or lumen 18 through the body. Body 16 is designed to conform to the shape and size of the abdominal portion of the esophagus, the esophageal-gastric junction and/or the proximal cardiac portion, or cardia, of the patient's stomach. The present invention is embodied in various bariatric devices. The devices may be removable, absorbable and/or permanent. The devices may be manufactured from a synthetic or a bioprosthetic material. While the invention is illustrated with a mesh wall, other configurations are possible, such as coil configurations, and the like. Bariatric device 15 may be positioned utilizing various techniques, such as endoscopic placement with fluoroscopic assist.

Wall 17 is configured to exert radial pressure at the abdominal portion of the esophagus, the esophageal-gastric junction and/or the cardia of the patient. This may be accomplished, for example, by configuring the wall to have a proximal portion 17a to create an interference fit with the abdominal portion of the esophagus and/or a central portion 17b configured to create an interference fit with the

esophageal-gastric junction and/or a distal portion 17c configured to create an interference fit with the patient's cardia. The pressure exerted by wall portions 17a, 17b and/or 17c influences the neurohormonal feedback mechanism present at the esophagus and/or stomach to cause at least partial satiety. As will be discussed in more detail below, the pressure exerted by the extendable wall may be fixed or adjustable. The force that influences the neurohormonal feedback mechanism present at the abdominal portion of the esophagus, the esophageal-gastric junction and/or the cardiac portion of the stomach is intended to be relatively consistent over as large an area as reasonably possible. The force exerted by the wall of the bariatric device is believed to activate stretch receptors located in the abdominal portion of the esophagus, the esophageal junction and/or the cardia. In contrast to prior proposed devices, which require that the patient ingest food in order to influence neurohormonal feedback mechanisms, bariatric device 15 simulates fullness in the absence of food. It also augments fullness caused by food.

This interference fit may be created by a self-extendable, or self-expanding, wall. Alternatively, it may be created by an extendable wall, such as a balloon-extendable wall. The extended wall diameter is chosen so that it is somewhat oversized compared to the diameter of the conduit in which it is positioned, namely, the abdominal portion of the esophagus, the esophageal-gastric junction and/or the cardia. A self-extendable wall may be, by way of example, laser cut from a Nitinol sheet, or may be a wall made from a self-extendable silicone-coated material. Alternatively, the wall may be extended by a balloon or fluid extendable reservoir expanding the wall radially outwardly to a position firmly against the wall of the conduit in which the body is inserted. This inflation may be accomplished endoscopically with a blunt needle or with a control as will be discussed in more detail below.

As can be seen in Fig. 1, wall 17 is longitudinally non-symmetrical with respect to the central longitudinal axis "L" defined by the direction of movement of the food along the patient's esophagus and stomach. In particular, as one moves along axis L, the cross-sectional configuration of wall 17 varies proximally to distally. For example, wall portions 17a and 17b are generally cylindrical in shape and wall portion 17c is frusto-conical in shape, flaring outwardly from a distal end of wall portion 17b. Wall portion 17c is angled to conform to the cardiac notch. Wall 17 may also be radially non-symmetrical with respect to this longitudinal axis

"L". In particular, certain portions of wall 17 are at a greater radial distance from axis L than portions of the wall at a different location around axis L. For example, wall portion 17c is enlarged at 19 to extend to more of the fundus of the cardia, such as the angle of His. This enlarged portion 19 makes wall 17 radially nonsymmetrical with respect to axis "L".

The narrow portion of lumen 18, which generally is the portion in the patient's esophagus, may have a length that is no longer required to provide enough radial force to produce satiety. In the illustrative embodiment, the narrow portion of lumen 18 is less than 9 cm in length. In certain embodiments, the narrow portion of lumen 18 is in the range of between 6 cm and 7 cm in length. This reduces the tendency of food to get caught in the lumen as well as any interference with peristalsis of the esophagus while producing radial force over a sufficient surface area to produce satiety.

In the embodiment illustrated in Fig. 1, bariatric device 15, and corresponding method of causing satiety in a patient, includes providing at least a portion 20 of middle wall portion 17b that does not exert a substantial radial pressure or force. Such portion may be made from a flaccid material, such as a non-self-expandable material. The device would be positioned such that the flaccid portion 20 covers the gastro-esophageal sphincter. This would allow the anti-reflux mechanism of the gastro-esophageal junction to operate generally normally because the wall of portion 20 would not exert any significant radial pressure on the sphincter. This embodiment allows the patient to belch, vomit, and the like, while resisting reflux. In bariatric device 15, proximal wall portion 17a is self-expandable and is generally cylindrical in shape to conform to the shape and size of the abdominal portion of the esophagus and distal wall portion 17c is self-expandable and is generally frusto-conically in shape to conform to the shape and size of the proximal cardiac portion of the stomach.

Bariatric device 15 may include a fixation system 21, which is capable of resisting distal migration of the device. Fixation system 21 may include a series of anchors 22 illustrated as a series of V-shaped downwardly directed appendages from wall 17. Alternatively, the anchors may be in the shape of downwardly directed barbs or hooks, metallic anchors extending radially from said body, or the like. Such arrangement provides fixation against distal migration while allowing the device to be easily removed from the patient because the anchors provide less

resistance to proximal movement. In the embodiment illustrated in Fig. 1, the anchors are positioned at or near the esophageal-gastric junction, such as proximally at distal portion 17c of the wall. This positioning of the anchor takes advantage of the fact that the esophageal gastric junction is thicker and, therefore, stronger at this location.

A bariatric device 115 includes a wall 117 having a proximal wall portion 117a that applies radial pressure to the abdominal portion of the esophagus, a distal portion 117c that applies radial pressure to the proximal cardiac portion of the stomach, and a middle portion 117b that is positioned at the esophageal-gastric junction (Fig. 2). As with bariatric device 15, in bariatric device 115 the central portion 117b is made from a non-expandable material, such as a flaccid material 120. Also, distal portion 117c includes an enlarged portion 119 that extends to more of the fundus of the cardia, such as the angle of His. Flaccid material 120 includes openings 123 that allow ingrowth of material. Openings 123 define at least in part a fixation system 121. Fixation system 121 may include a secondary, or temporary, means for anchoring bariatric device 115 while allowing tissue to ingrow through openings 123. Such secondary fixation system may include stitches, staples, or the like. Openings 123 may be sized appropriately to accept such stitches or staples. The sutures could be dissolvable or non-dissolvable. Openings 123 may be as few as, for example, five openings in the flaccid material portion 120. Alternatively, they may be a lattice of small holes that allow tissue ingrowth. The use of tissue ingrowth utilizes the body's reaction to the bariatric device 115 in order to assist in fixing the device against distal migration. While some irritation of the mucosa may occur when bariatric device 115 is removed, any such irritation should be relatively minor and readily healed. As with all fixation systems described herein, fixation system 121 may be used in combination with other fixation systems, such as fixation system 21, or the like.

An alternative bariatric device 215 includes a body 216 having an expandable wall 217 (Figs. 4 and 5). Expandable wall 217 defines an internal chamber 24 throughout at least a portion of the proximal portion 217a, middle portion 217b and distal portion 217c of wall 217. Chamber 24 may be a single unitary chamber that extends the length of wall 217 or may be a series of separate chambers that are either interconnected or separated from each other. For example, a chamber may be positioned around proximal portion 217a of wall 217 that is sized

and shaped to be positioned at the patient's abdominal esophagus and a chamber may be positioned at distal portion 217c that is sized and shaped to be positioned at the patient's cardia while no chamber is present at all or a portion of 217b that is configured in size to be at the esophageal-gastric junction of the patient. In this manner, wall 217 would not be substantially expandable at the gastro-esophageal sphincter, thereby reducing interference with normal operation of such sphincter, as previously discussed.

As can be seen in Fig. 4, a port 25 may be provided to chamber 24 in order to allow access by a needle 26 connected with a device 27 that is endoscopically inserted in the patient and used to either add fluid to or remove fluid from chamber 24. In this manner, the amount of radial force exerted by wall 217 may be varied or adjusted. In this manner, for example, a greater amount of radial force may be applied to a morbidly obese patient, such as one that is more than 40 pounds overweight, while a lower amount of radial pressure may be applied to patients that are overweight or mildly obese, such as those that are 30 to 40 pounds overweight, for example. Bariatric device 25 is illustrated with a fixation system in the form of anchors 22, although other fixation systems previously described may be utilized. Additionally, distal portion 217c may be radially symmetrical with respect to the longitudinal axis "L" of the device or may be non-symmetrical by including the enlarged portion of distal wall portion 217c as previously described.

As illustrated in Fig. 5, reservoir 24 of bariatric device 215 may, alternatively, be connected with a fluid reservoir 28 positioned within the patient and including a control 29 that is configured to selectively transfer between fluid reservoir 24 in the bariatric device and fluid reservoir 28 in the patient. In this manner, control 29 may control the amount of fluid in fluid chamber 24, thereby adjusting the amount of radial force exerted by the wall 217 of the device on the conduit in which it is positioned. An optional patient operable control 31 may be provided and interconnected with internal control 29, such as by a radio-frequency link 32, in order to allow a patient or medical attendant to modify the amount of pressure exerted by wall 217.

Control 29 may provide for a temporal adjustment of the amount of radial pressure exerted by bariatric device 215 on the patient's distal esophagus and/or proximal stomach. By way of example, control 29 may include an algorithm that causes fluid to be transferred from fluid reservoir 30 to fluid chamber 24 of the

device 215 in order to increase the amount of radial pressure exerted by wall 217 during general waking hours of the patient when satiety is desired. Control 29 can further be programmed to transfer fluid from reservoir 24 to reservoir 30 during periods of time when the patient is expected to be sleeping and satiety is not required. Patient control 31 may, alternatively, allow manual adjustment of the amount of radial force exerted by wall 214 of device 215. For example, when the patient retires at night, the patient may operate user control 31 in order to instruct control 29 to transfer fluid from chamber 24 to fluid reservoir 30, thereby reducing pressure exerted by wall 217. When the patient awakes, the patient may then utilize user control 31 in order to cause control 29 to increase the amount of radial pressure exerted by wall 217. This temporal control of the amount of force exerted by wall 217 should overcome any potential tachy phylaxis that may result in the diminishing response of the neurohormonal system of the patient to the radial force exerted by wall 217. Alternatively, the temporal control may be utilized, where appropriate, to adjust the amount of radial pressure with respect to eating times of the patient, or the like. Control 29 may, alternatively, monitor certain hormonal levels of the patient in order to determine when the patient is expected to eat a meal and may even be a self-learning control system in order to learn the variations in the patient's hormonal levels.

An alternative bariatric device 315 may further include a restriction component 33 restricting discharge of food from lumen 18 (Fig. 6). Restriction component 33 may be in the form of a chamber 34 extending within the lumen of body 316. In the illustrative embodiment, restriction component 33 is adjacent to distal portion 317c of wall 317, but could be at other locations along wall 317. Chamber 34 may be increased or decreased in volume utilizing various techniques, such as by adding or withdrawing a fluid, such as a gas or a liquid, via a blunt needle 26 (Fig. 7). Other known devices, such as an external electronic device that communicates with a control (not shown) and a pump/fluid reservoir within the patient, may be used to adjust the size of restriction component 33. With such configuration, the external control may actuate the pump through the internal control in order to increase or decrease the size of chamber 24. Alternatively, the internal control may be programmed to carry out the adjustment. Chamber 28 restricts the cross-section of lumen 18. Such restriction resists egress from lumen 18 of walls 16

and thereby resists the continued ingestion of food past device 315. This may be useful in patients who tend to continue to eat past satiety.

Fig. 8 illustrates an alternative bariatric device 415 having a body 416 with a restriction component 133 in the form of an inflatable reservoir or chamber 134 which surrounds the distal portion 418a of the lumen 418. Reservoir 134 provides an adjustable restriction wherein, as additional fluid is added to chamber 134, the increase in the volume of the chamber restricts the diameter of lumen 418 thereby adjusting the ability to resist egress from the lumen of bariatric device 415 thereby providing a variable restriction to ingestion of food. Chamber 134 may also be capable of increasing the external diameter of the device wall 417c thereby placing additional pressure on stretch receptors at the cardia of the patient's stomach.

An alternative bariatric device 515 may include a body 516 having a wall 517 including an anti-reflux component 35 (Fig. 9). Anti-reflux component 35 may be in the form of a one-way valve in order to resist reflux from the stomach to the esophagus. As best seen in Fig. 9, anti-reflux component 35 may be in the form of a tubular extension of lumen 518 that expands to allow distal movement of food but collapses to reduce reflux.

An alternative bariatric device 615 includes a body 616 having a wall 617 that is self-expandable at a proximal portion 617a, a middle portion 617b and a distal portion 617c, the latter being configured to the cardiac notch of the patient (Fig. 10). Bariatric device 615 includes a fixation system 21, such as a series of anchors 22, at the esophageal-gastric junction of the patient. The entire surface of wall 617 is made of a self-expanding material.

An alternative bariatric device 715 illustrated in Fig. 11 has a body 716 in which egress from the lumen 718 is from a discharge portion 40 of the device located at or near the patient's intestines. This provides additional weight loss by substantially bypassing the patient's stomach and discharging to the intestines. Device 715 may include a series of perforations 36 at discharge portion 40 in order to distribute the egress from lumen 718 along the small intestine of the patient. Use of bariatric device 715 may require dietary restrictions to avoid food collection in the elongated lumen.

Anchors may be positioned at various locations along the exterior of the wall of the device. For an example, an alternative bariatric device 815 is illustrated in Fig. 12 with a body 816 having a wall 817 having anchors, such as V-shaped

appendages, barbs, or hooks distributed along the outer wall of the body. The fixation system may also be in the form of a balloon-expandable wall 817c defining a chamber 37 that applies sufficient pressure on the conduit in which the device is located in order to resist distal migration of the device. The balloon can extend the device wall to produce fixation and can be deflated in order to allow the device to be removed. Fig. 13 illustrates an alternative bariatric device 815' having a body 816 with a wall 817 defining a lumen 818 without a chamber. Other fixation systems may be apparent to the skilled artisan, such as stitching, stapling, and the like.

An alternative bariatric device 915 illustrated in Fig. 14 includes a body 916 having a wall 917 that is positioned virtually entirely within the patient's stomach. Wall 917 is of a size and shape to conform to the cardiac portion of the stomach, cardia, and is configured to exert radial pressure on the cardia. Device 915 includes a fixation system 922 that engages the cardia or the esophageal-gastric junction.

Various delivery systems may be utilized to deliver any of the bariatric devices 15-915 to the patient. Such a delivery system may include a tube device (not shown) into which the bariatric device is compressed. The tube device may be a stiff or flexible tube and be sized and shaped to easily fit within the patient's esophagus. Such a delivery system includes a deployment mechanism (not shown) to retract the bariatric device from the tube. As the bariatric device is removed from the tube, it assumes its expanded form. If a self-expanding wall is utilized, the bariatric device will assert radial pressure on the distal esophagus and/or the cardia of the patient when removed from the tube. If an expandable wall is utilized, such as a bladder, the bladder is inflated in order to exert radial pressure. Various markers, such as fluorescent markers, may be applied to the wall of the bariatric device in order to allow for fluoroscopic assist in the placement of the device.

A method 50 may be provided for monitoring and, if desired, adjusting the amount of satiety produced by the bariatric device and method (Fig. 15). In method 50, a bariatric device 15-915 is inserted in the patient at 52 and a level of radial pressure is applied by the body wall of the device. The level of satiety is monitored, such as by monitoring the patient's hypothalamus at 54, such as with a Positron Emission Tomography (P.E.T.) scan. The P.E.T. scan produces a visual image of the hypothalamus that changes colors with the amount of activity of the hypothalamus. By observing the color of the hypothalamus through the P.E.T. scan,

a determination is made at 56 whether an appropriate level of satiety is obtained. If it is, then the procedure is done at 58.

If it is determined at 56 that an appropriate level of satiety is not being obtained, the process returns to 52 where a different level of radial pressure may be adjusted by the body. The adjustment of pressure may be in the form of adding or subtracting fluid from a bariatric device having an expandable wall by the use of a chamber 24. Alternatively, the adjustment of the radial pressure may be in the form of deploying a different size or characteristic device which is self-expandable and applies a different force to the patient through the self-expandable wall. The amount of satiety may be different for different patients. For example, a patient who is overweight may require a particular level of radial pressure, whereas a more obese, such as a morbidly obese, patient may require a higher level of satiety. Likewise, a child or an adolescent may require different levels of radial pressure. The ability to obtain immediate feedback on satiety strength allows the efficacy of the system to be established at deployment rather than monitoring the patient for weight loss and adjusting it after the patient has lost either too much or too little weight.

Any of the bariatric devices 15-915 may be used as part of a multi-disciplinary comprehensive program. This may include the adjustment of medications as the patient experiences weight loss. For example, for patients taking diabetic medications, less insulin may be required as a patient loses weight. Also, blood pressure medications and other medications may be adjusted as the patient loses weight.

Because of the ability of the bariatric device 15-915 to cause satiety, it is possible, in certain patients, that the patient will require nutritional supplements, such as protein liquids, in order to ensure adequate nutritional needs, such as protein intake. Also, anti-nausea medications may be given to the patient, especially at the beginning of the placement. This is because a bariatric device, according to the invention, may cause nausea at the beginning of the placement.

In order to reduce the likelihood of food getting caught in the lumen and in order to minimize interference with natural peristalsis in the esophagus, the length of the lumen is generally kept below 9 cm. In most embodiments, the length of the lumen is in the range of approximately 6 cm to approximately 7 cm. Widened portions of the body, such as distal portions 17c-917c, are not considered part of the lumen for determining the length of the lumen. The expandable wall, whether self-

expanding or balloon-expandable, should provide consistent pressure over as large an area as possible in order to induce adequate satiety, consistent with an effort to keep the lumen as short as possible.

Thus, it is seen that the present invention introduces a new category of weight loss techniques: implied satietion. The invention advantageously utilizes stretch receptors, such as those located at the abdominal portion of the esophagus and/or esophageal-gastric junction and/or the cardiac portion of the stomach of the patient to cause satiety. In contrast to gastric bypass surgery and adjustable gastric bands, the present invention does not require surgical intervention. In that regard, the present invention provides a non-invasive or minimally invasive alternative. However, the invention may be utilized in combination with known restrictive and/or malabsorptive techniques, such as gastric bypass surgery and adjustable gastric bands to further help the patient lose weight. Advantageously, the present invention may be applied to patients who are contraindicated for surgery, such as those with mildly high obesity and for those at risk for surgery. Also, the invention may be used to achieve sufficient weight loss in morbidly obese patients to stabilize the patient for gastric bypass surgery. Moreover, the present invention may be properly sized for use with children and adolescence. Thus, the present invention provides a non-intrusive or minimally intrusive technique for addressing the increasing epidemic of obesity in adolescents and children, as well as adults.

The present invention also comprehends an implied satietor that is capable of exerting radial pressure at the patient's abdominal portion of the esophagus, esophageal-gastric junction and/or cardia, such as by suitable dimensioning of a self-expanding wall or by a mechanism for expanding the wall outwardly. Examples of such a mechanism may be a bladder mechanism whereby the wall could exert varying radial pressures. The present invention also has the capability of assisting in reducing esophageal leakage. This may further enhance the use of the invention in combination with other techniques, such as gastric bypass surgery, esophageal tumors, and the like. In addition to influencing the neurohormonal feedback mechanism present at the abdominal portion of the esophagus, the present invention is capable of resisting egress from the lumen of the satiety device. This provides additional benefit to certain patients by resisting their ability to ingest food beyond satiety. Because the device may be inserted endoscopically with fluoroscopic assist, the device may be suitably and accurately positioned at the desired location within

the patient's esophagus, esophageal-gastric junction and/or cardia and adjustments made to the satiety device as required. Moreover, the device may be subsequently removed from the patient if indicated. The use of various fixation systems allow the device to be positioned at or near the abdominal portion of the esophagus, the esophageal-gastric junction and/or the cardia while resisting distal migration of the device. Moreover, the use of such fixation system may allow for the satiety device to be readily removed from the patient.

Evidence of the viability of the invention can be seen by its principle having been reduced to practice and found to cause weight loss in 8 patients. The patients, who ranged from non-obese to morbidly obese, lost an average of approximately 7 pounds per week, generally over a one or two week period during which the device was in place. The patients experienced some initial nausea. They reported satiety throughout placement of the device. When the device was no longer present, the patients regained hunger.

Changes and modifications in the specifically described embodiments can be carried out without departing from the principles of the invention which is intended to be limited only by the scope of the appended claims, as interpreted according to the principles of patent law including the doctrine of equivalents.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A bariatric device, comprising:

a body having a wall defining a lumen, said wall configured to generally conform to the shape and size of at least one chosen from i) the abdominal portion of the esophagus, ii) the esophageal-gastric junction, and iii) the proximal cardiac portion of the stomach, said wall adapted to exert radial pressure on the at least one chosen from i) the abdominal portion of the esophagus, ii) the esophageal-gastric junction, and iii) the proximal cardiac portion of the stomach, thereby influencing a neurohormonal feedback mechanism of the patient to cause at least partial satiety by augmenting fullness caused by food and simulating fullness in the absence of food.

2. The bariatric device as claimed in claim 1 wherein said body is elongated along a longitudinal axis and wherein said body is longitudinally non-symmetrical with respect to said longitudinal axis.

3. The bariatric device as claimed in claim 2 wherein at least a portion of said body is radially non-symmetrical with respect to said longitudinal axis.

4. The bariatric device as claimed in any of the preceding claims wherein said wall is sized to generally conform to the size and shape of the abdominal portion of the esophagus, the esophageal-gastric junction and the proximal cardiac portion of the stomach and said wall is adapted to exert radial pressure at least on the abdominal portion of the esophagus and the proximal cardiac portion of the stomach.

5. The bariatric device as claimed in any of the preceding claims wherein said body has first and second geometrical portions, said first geometrical portion being generally cylindrical, said second geometric portion being generally frusto-conical.

6. The bariatric device as claimed in any of the preceding claims wherein said wall includes a self-expanding portion that is adapted to exert radial pressure and a substantially non-self-expanding portion that is adapted to not exert radial pressure.

7. The bariatric device as claimed in claim 6 wherein said non-self-expanding portion is adapted to be positioned at the gastro-esophageal sphincter.

8. The bariatric device as claimed in any of the preceding claims wherein said wall is adapted to exert a generally constant radial pressure.

9. The bariatric device as claimed in any of claims 1 through 5 wherein said wall is adapted to exert an adjustable radial pressure.

10. The bariatric device as claimed in claim 9 wherein said wall defines a chamber wherein an amount of fluid in said chamber adjusts the radial pressure exerted by said wall.

11. The bariatric device as claimed in claim 10 including a port providing external access to said chamber.

12. The bariatric device as claimed in any of claims 9 through 11 including a control, said control is adapted to controlling an amount of radial pressure exerted by said wall.

13. The bariatric device as claimed in claim 12 wherein said control is adapted to temporarily adjust an amount of radial pressure exerted by said wall.

14. The bariatric device as claimed in any of the preceding claims including at least one fixation mechanism that is adapted to resist distal migration of said body.

15. The bariatric device as claimed in claim 14 wherein said fixation mechanism includes at least one chosen from barbs, V-shaped appendages, metallic anchors extending radially from said body, staples and sutures.

16. The bariatric device as claimed in claim 14 wherein said fixation mechanism includes an inflatable anchor bladder.

17. The bariatric device as claimed in claim 14 wherein said fixation mechanism includes at least a portion of said body being adapted to facilitate tissue ingrowth.

18. The bariatric device as claimed in any one of claims 14 through 17 wherein said fixation mechanism is at a portion of said wall adapted to be positioned at the esophageal-gastric junction.

19. The bariatric device as claimed in any of the preceding claims including a restriction to resist egress from said lumen.

20. The bariatric device as claimed in claim 19 wherein said restriction comprises an adjustable restriction.

21. The bariatric device as claimed in claim 20 wherein said adjustable restriction comprises a fluid reservoir, said adjustable restriction being adjustable by varying a fluid in said reservoir.

22. The bariatric device as claimed in claim 21 wherein said adjustable restriction is adjustable by one chosen from (a) an externally accessible port for adding to or removing a fluid from said reservoir and (b) an electronic control device for controlling an amount of fluid in said reservoir.

23. The bariatric device as claimed in any of the preceding claims wherein said lumen has a length that is less than 9 cm.

24. The bariatric device as claimed in claim 23 wherein said lumen has a length that is in the range of between approximately 6 cm and approximately 7 cm.

25. A method of causing at least partial satiety in a patient, comprising:

providing a body having a wall defining a lumen;

positioning said body at at least one chosen from i) the abdominal portion of the esophagus, ii) the esophageal-gastric junction and (iii) the proximal cardiac portion of the stomach; and

exerting radial pressure with said wall on the at least one chosen from i) the abdominal portion of the esophagus, ii) the esophageal-gastric junction and (iii) the proximal cardiac portion of the stomach, thereby influencing a neurohormonal feedback mechanism of the patient to cause at least partial satiety by augmenting fullness caused by food and simulating fullness in the absence of food.

26. The method as claimed in claim 25 wherein positioning includes positioning said body at the abdominal portion of the esophagus, the esophageal-gastric junction and the proximal cardiac portion of the stomach and wherein said exerting includes exerting radial pressure with said wall at least on the abdominal portion of the esophagus and the proximal cardiac portion of the stomach.

27. The method as claimed in claim 26 including providing a substantially flaccid portion of said wall, and positioning said substantial flaccid portion at the gastro esophageal sphincter to reduce interference with the anti-reflux mechanism of the patient.

28. The method as claimed in any of claims 25 through 27 including fixing said body to the patient to resist distal migration of said body.

29. The method as claimed in claim 28 including fixing said body at the esophageal-gastric junction.

30. The method as claimed in claim 28 or claim 29 wherein said fixing includes facilitating ingrowth of tissue through said wall.

31. The method as claimed in any of claims 25 through 30 wherein said exerting radial pressure includes exerting a generally constant radial pressure.

32. The method as claimed in any of claims 25 through 30 wherein said exerting radial pressure includes exerting an adjustable radial pressure.

33. The method as claimed in claim 32 wherein said exerting an adjustable radial pressure includes adjusting the pressure endoscopically.

34. The method as claimed in claim 32 wherein said exerting an adjustable radial pressure includes adjusting the pressure with a control at least partially positioned at the patient.

35. The method as claimed in any of claims 32 through 34 wherein said exerting an adjustable pressure includes adjusting the pressure according to a temporal parameter.

36. The method as claimed in claim 35 wherein said adjusting the pressure according to a temporal parameter includes decreasing the pressure during expected sleeping periods.

37. The method as claimed in any of claims 25 through 36 including monitoring patient satiety caused by said exerting radial pressure.

38. The method as claimed in claim 37 wherein said monitoring includes monitoring patient satiety during deployment of said body in a patient.

39. The method as claimed in claim 37 or claim 38 including selecting a radial pressure as a function of said monitoring.

40. The method as claimed in any of claims 37 through 39 wherein said monitoring includes monitoring activity of the patient's hypothalamus.

41. The method as claimed in any of claims 25 through 40 including administering anti-nausea medication to the patient at least during initial deployment of said body.

42. The method as claimed in any of claims 25 through 41 including administering nutritional supplements to the patient.

43. The method as claimed in any of claims 25 through 42 wherein said positioning comprises endoscopic positioning.

44. The method as claimed in claim 43 wherein said endoscopic positioning includes fluoroscopic assist.

45. The method as claimed in any of claims 25 through 44 including restricting egress of food from said lumen.

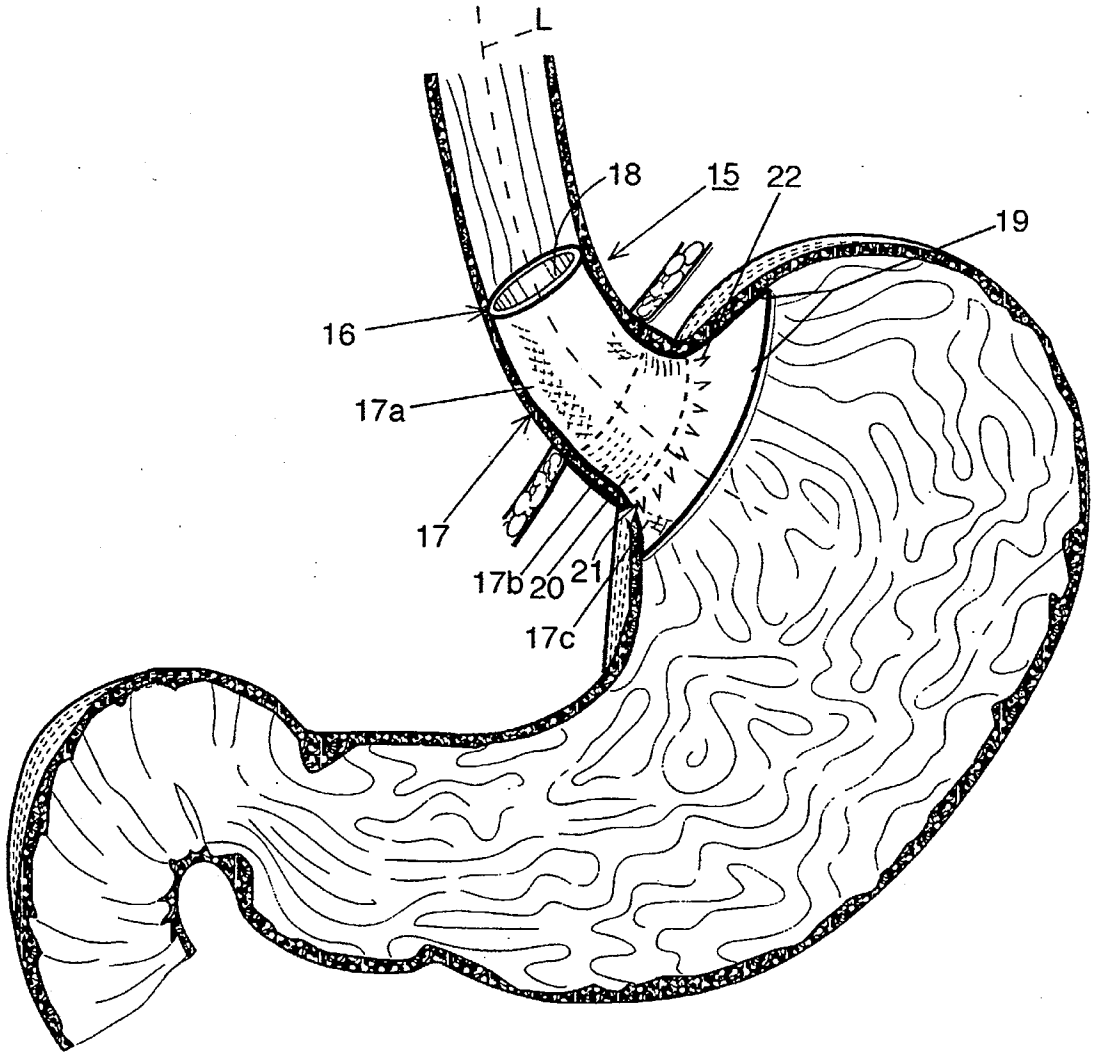

Fig. 1

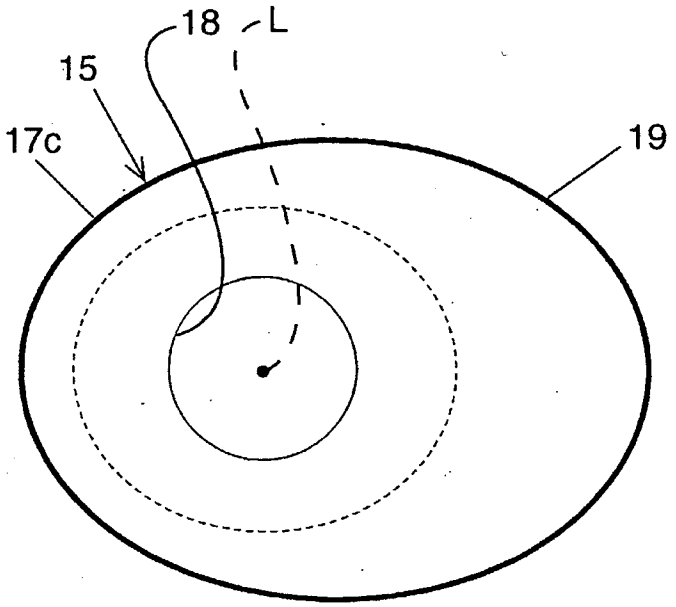

Fig. 2

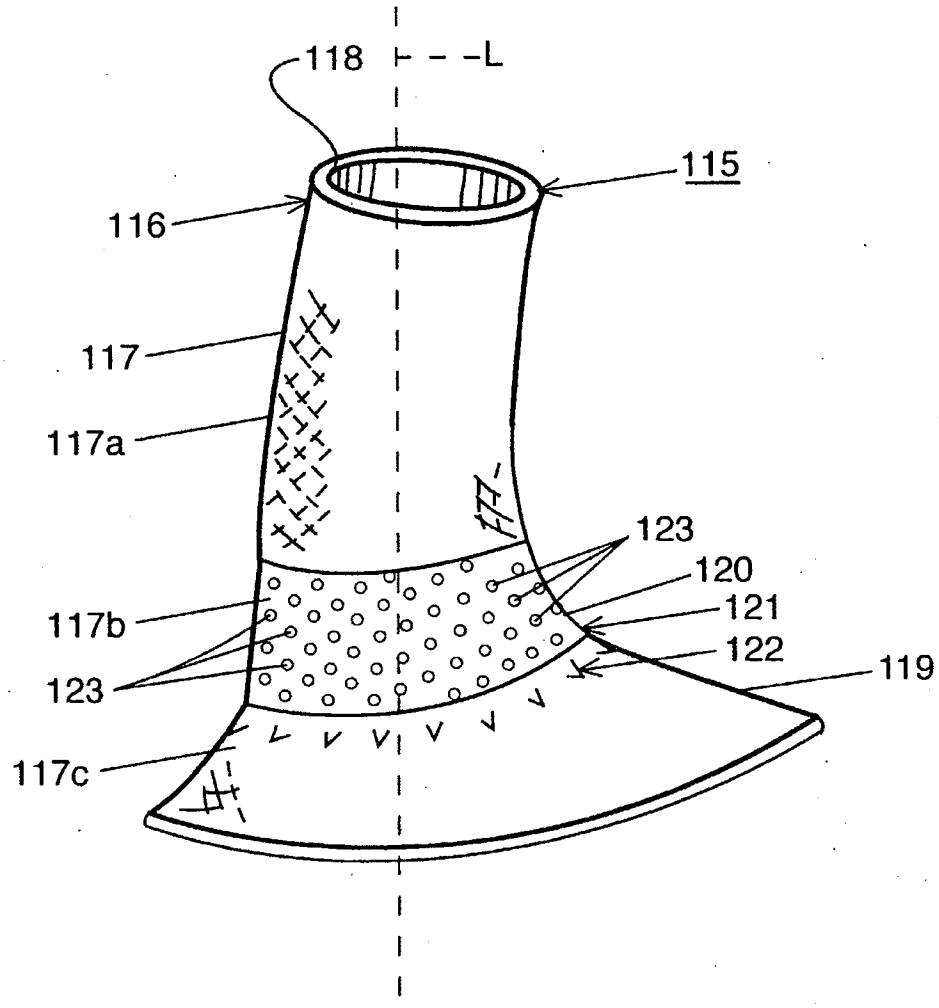

Fig. 3

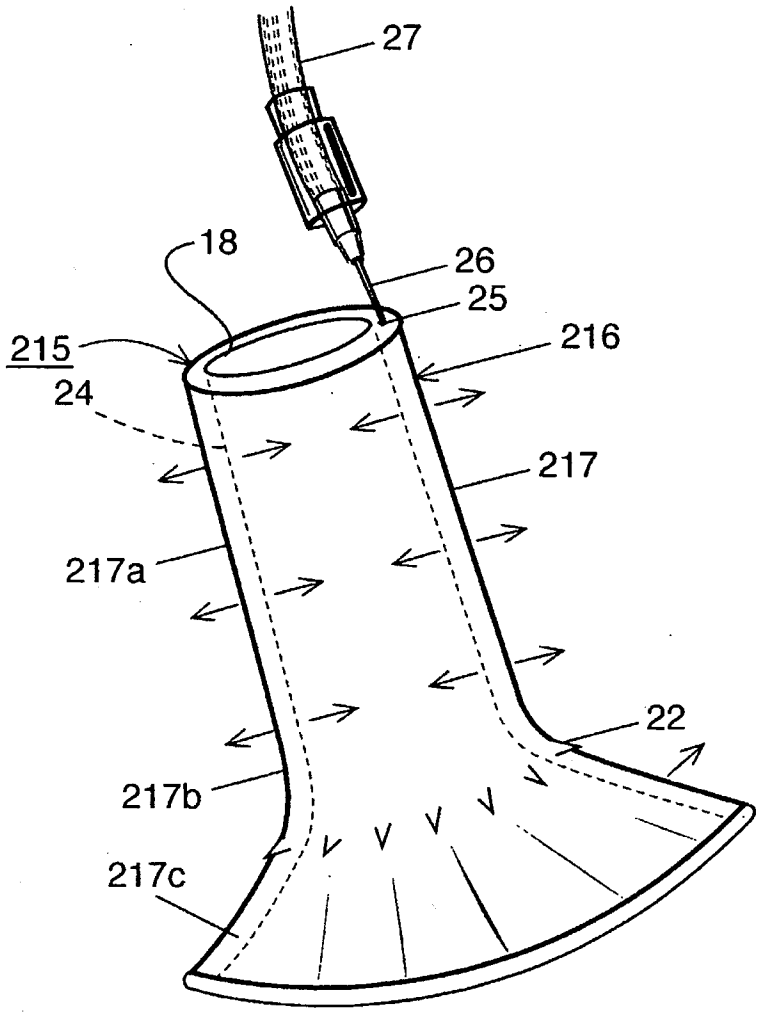

Fig. 4

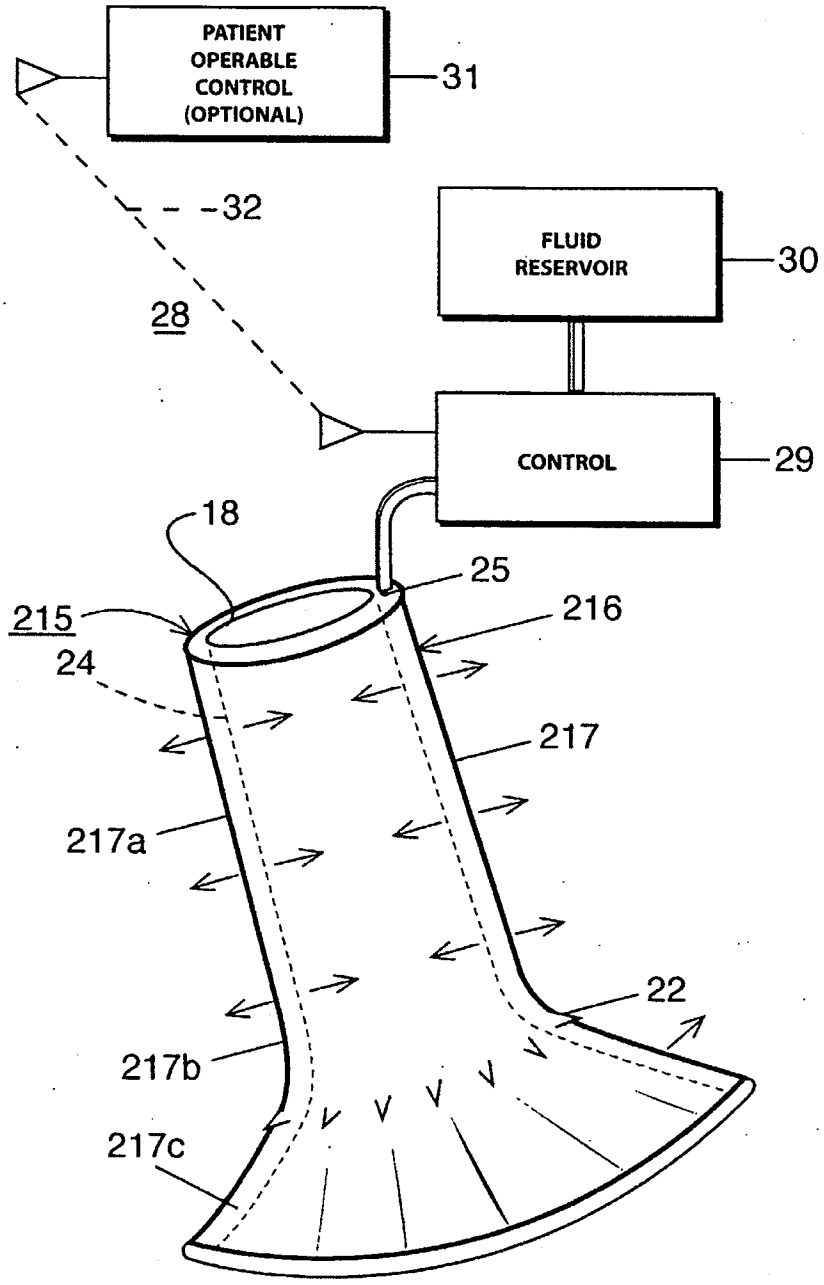
PATIENT OPERABLE CONTROL (OPTIONAL)
31
32
28
FLUID RESERVOIR
30
CONTROL
29
18
25
215
216
24
217
217a
22
217b
217c

Fig. 5

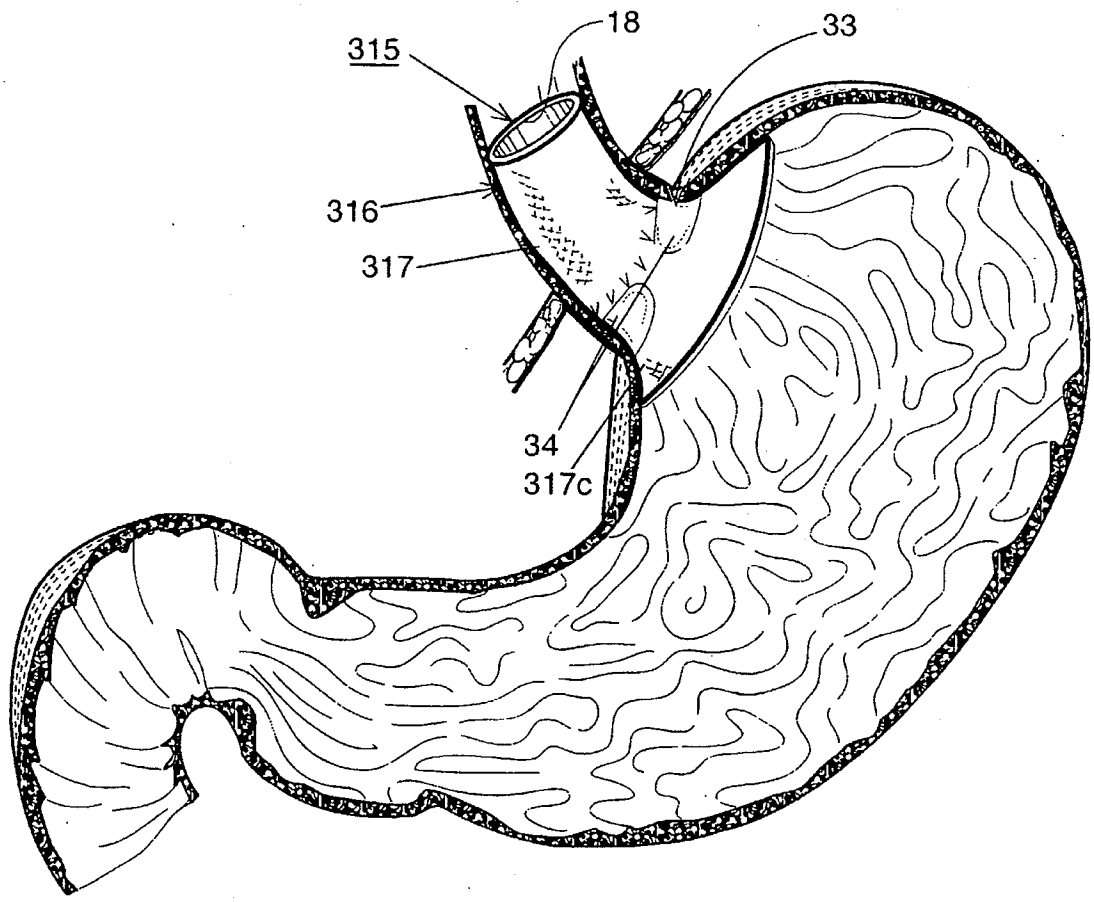

Fig. 6

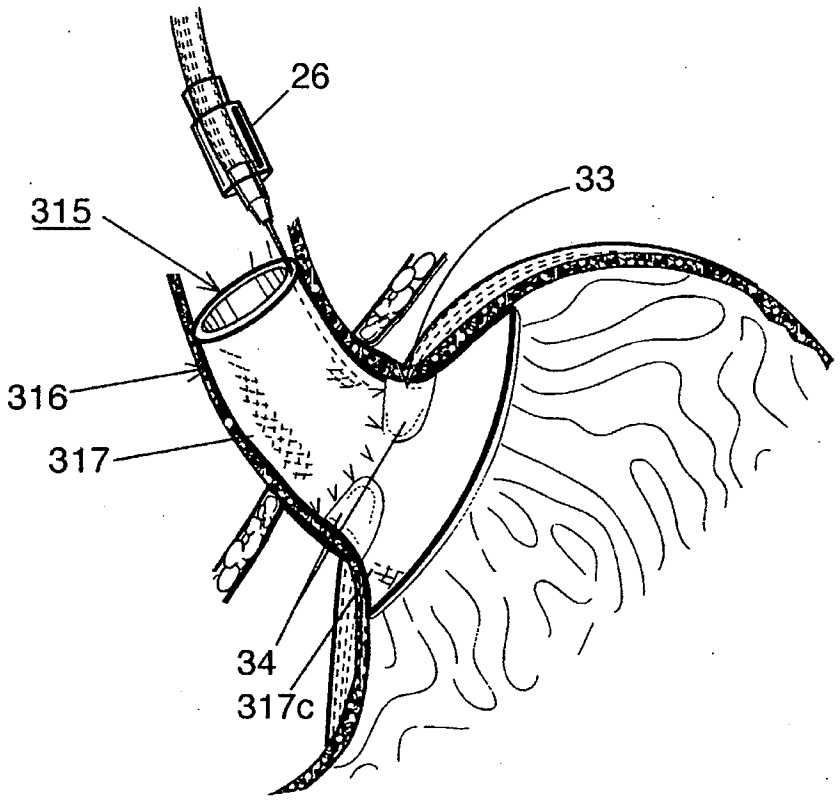

Fig. 7

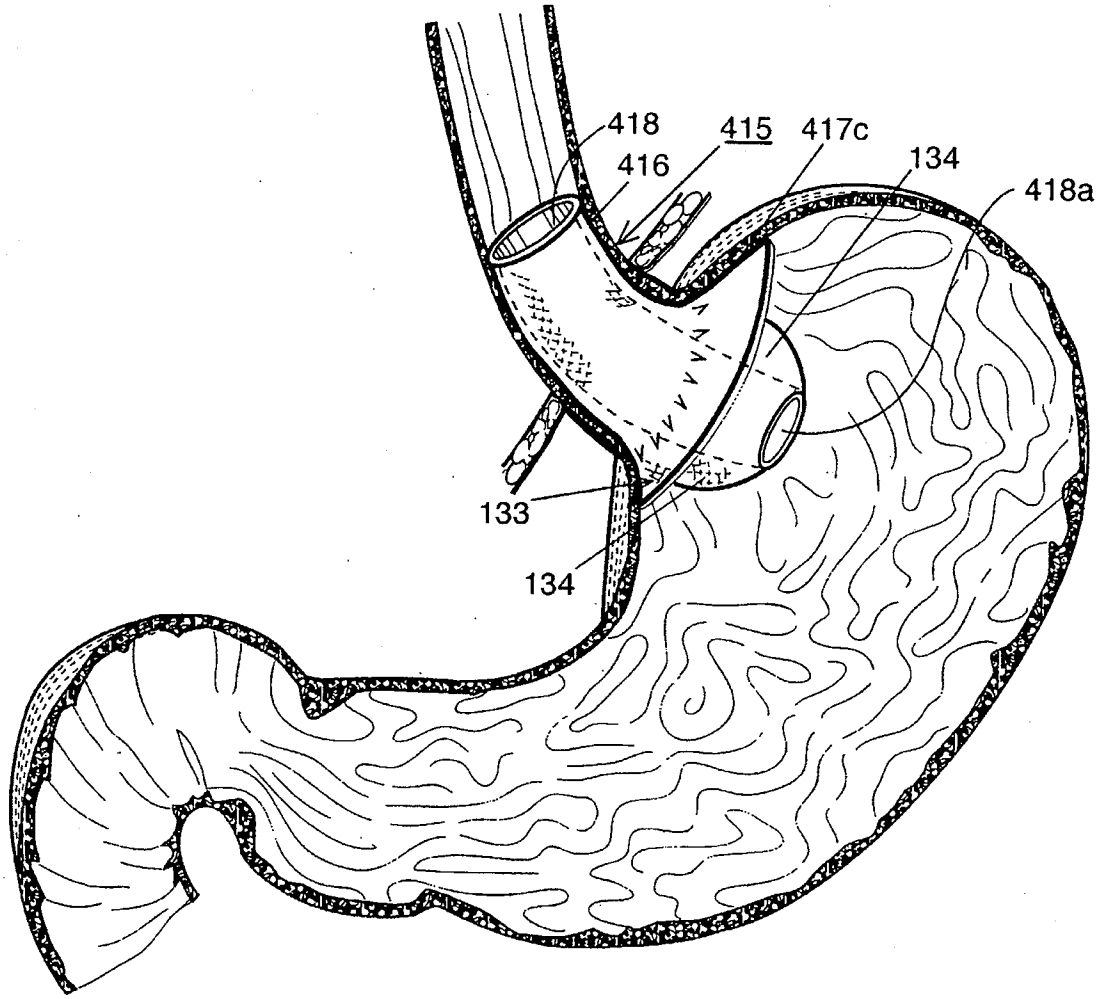

Fig. 8

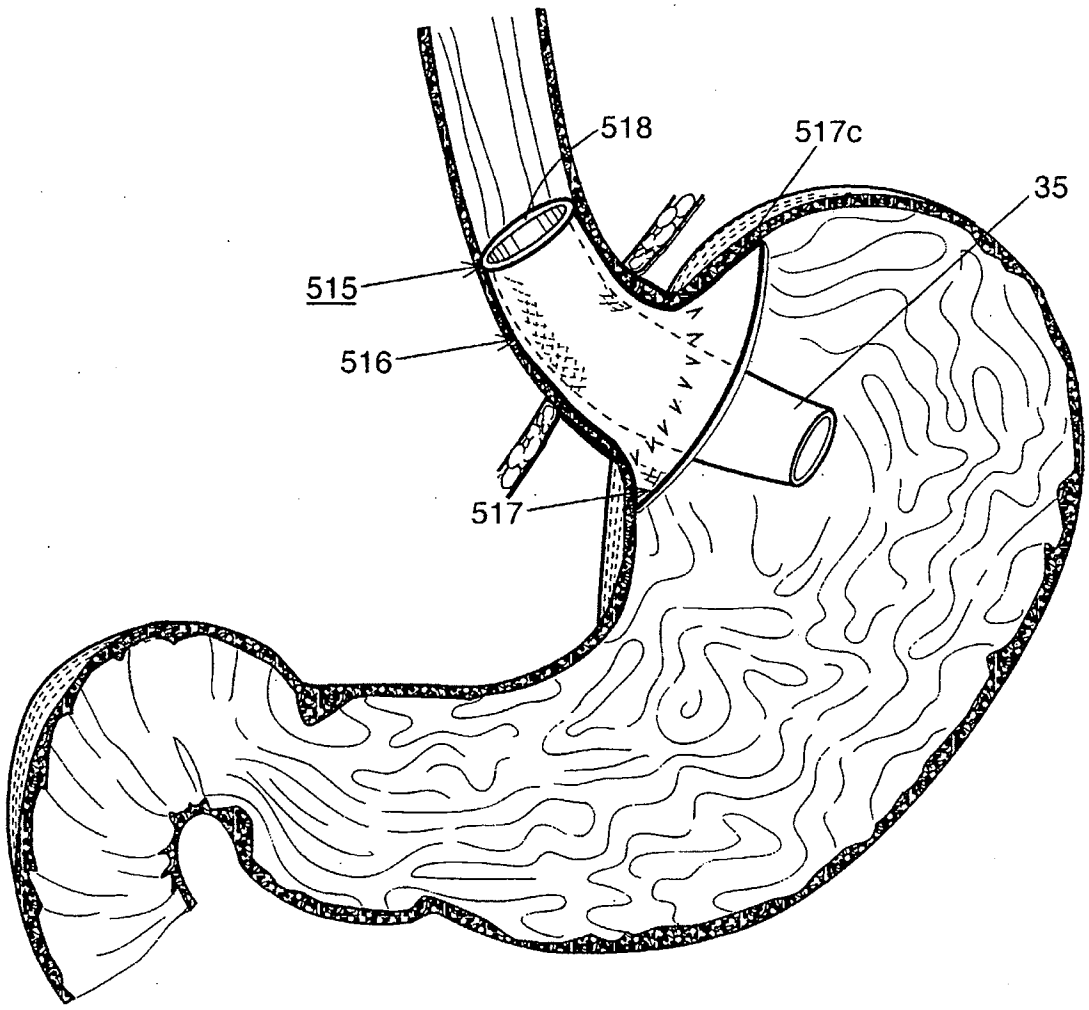

Fig. 9

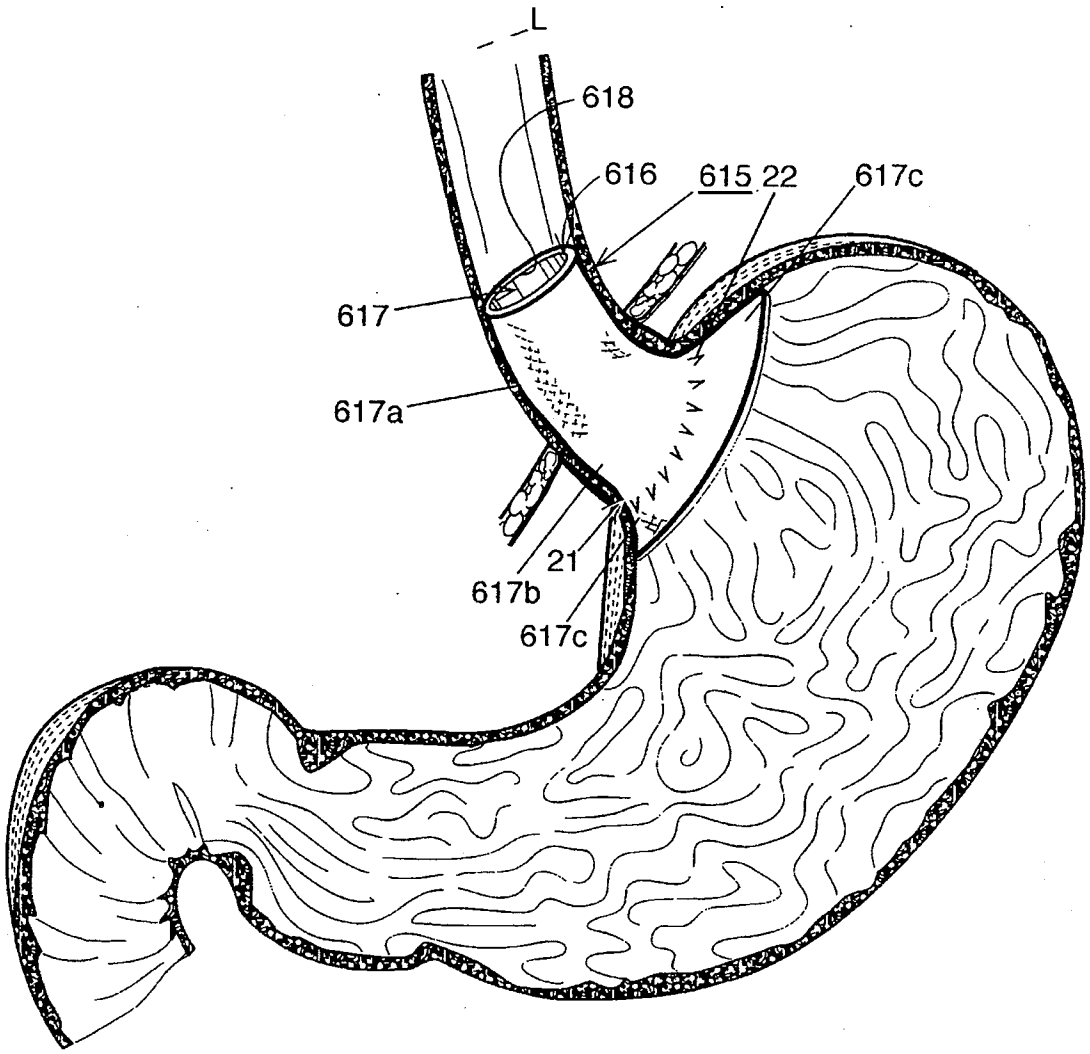

Fig. 10

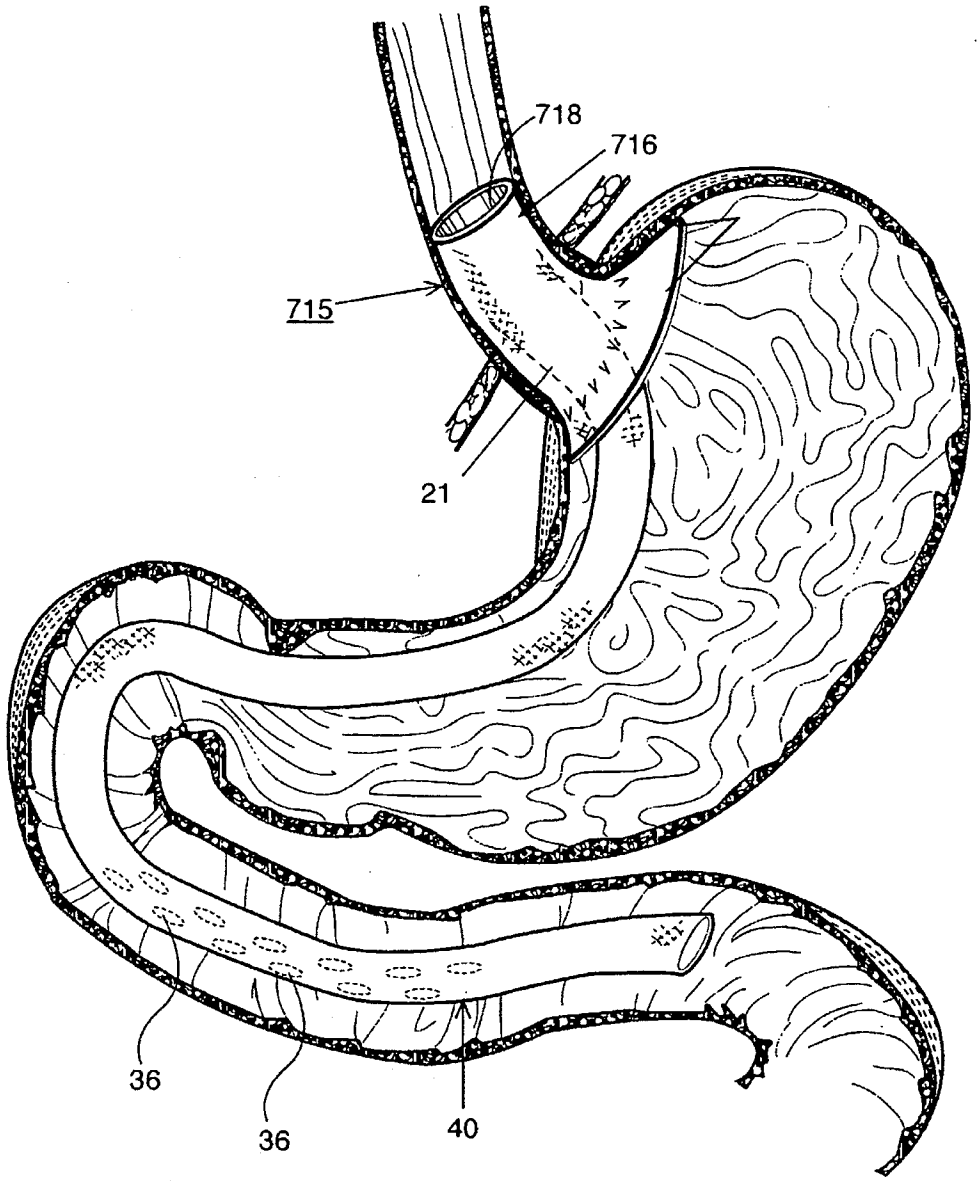

Fig. 11

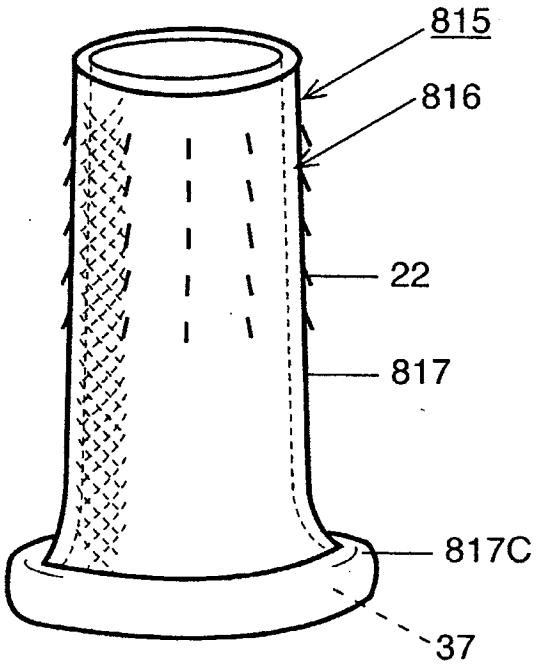

Fig. 12

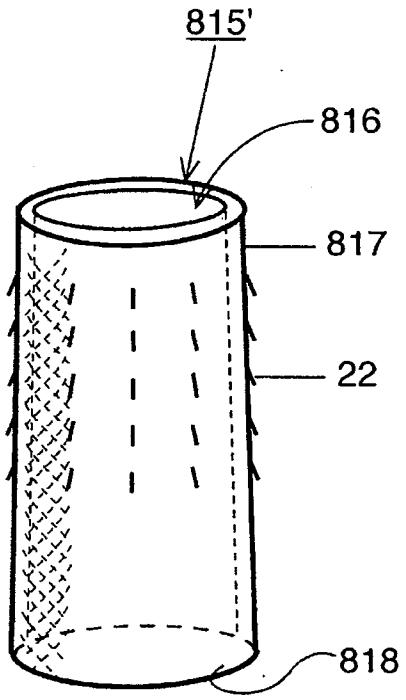

Fig. 13

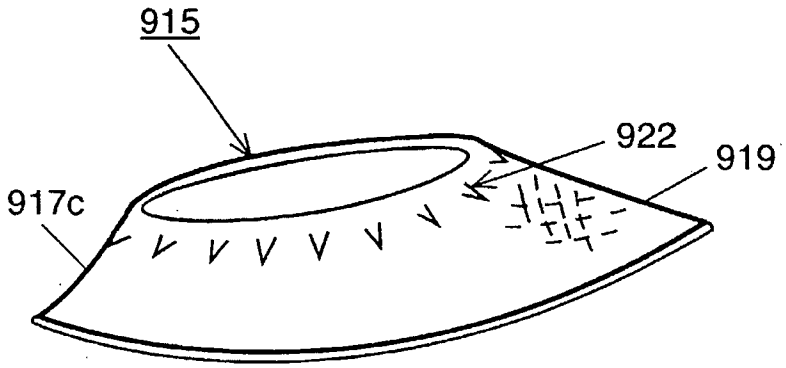

Fig. 14

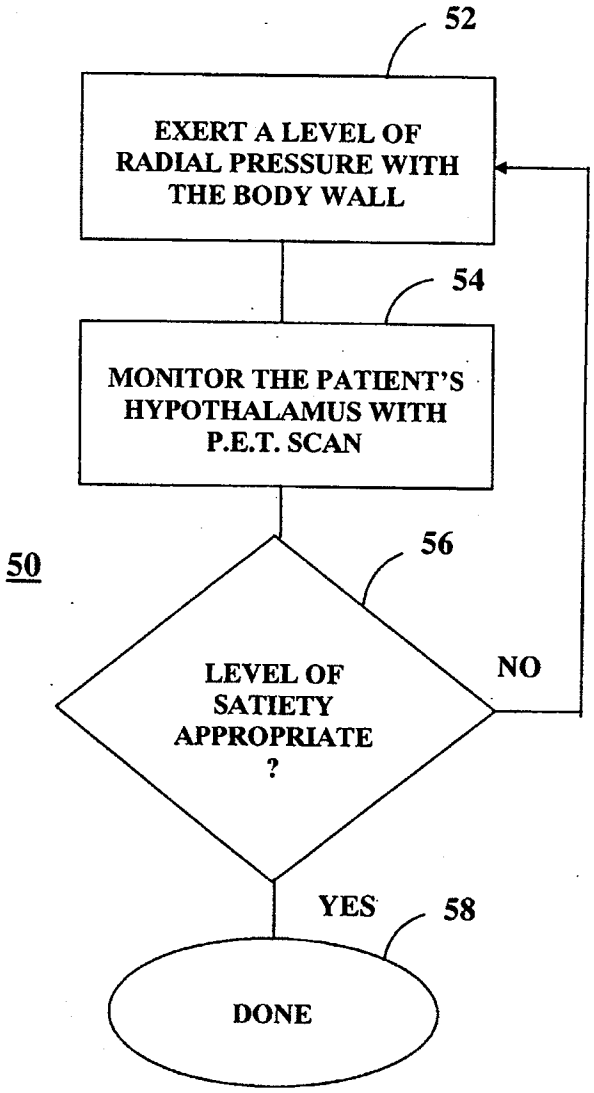
52
EXERT A LEVEL OF RADIAL PRESSURE WITH THE BODY WALL
54
MONITOR THE PATIENT'S HYPOTHALAMUS WITH P.E.T. SCAN
50
56
LEVEL OF SATIETY APPROPRIATE ?
NO
YES
58
DONE

FIG. 15

INTERNATIONAL SEARCH REPORT

International application No
PCT/US05/36991

A CLASSIFICATION OF SUBJECT MATTER
IPC. **A61M 29/00**(2006 01)

USPC 604/96.01
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U S. Please See Continuation Sheet

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
A	US 6,572,627 B2 (Gabbay) 03 June 2003 (03.06.2003) Note. Please review the entire patent	1-45
A	US 4,403,604 A (Wilkinson et al.) 13 September 1983 (13.09.1983) Note Please review the entire patent.	1-45

☐ Further documents are listed in the continuation of Box C ☐ See patent family annex.

* Special categories of cited documents·

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
06 March 2006 (06.03.2006)

Date of mailing of the international search report
31 MAR 2006

Name and mailing address of the ISA/US
Mail Stop PCT, Attn. ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (571) 273-3201

Authorized officer
Manuel Mendez

Telephone No. 703-000-000

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/36991

Continuation of B. FIELDS SEARCHED Item 1:
604/96 01, 101.01, 915, 916
606/191-194